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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,380	07/12/2001	Jane H. Morse	62430-A/IPW/SHS	1634
7590 03/05/2004			EXAMINER	
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,380

Applicant(s)

MORSE ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 51-53, 55-57, 59, 60, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) 53, 55, 57, 59 and 60 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56 is/are allowed.
- 6) ☒ Claim(s) 1-5, 51 and 52 is/are rejected.
- 7) ☒ Claim(s) 64 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. It is initially noted that claims 53, 55, 57, 59, and 60 are still withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims encompass methods of detecting the broad genus of any possible mutation in the bone morphogenetic protein receptor-II (BMPRII) nucleic acid or protein, and correlating such a mutation with a pulmonary disease, giving birth to twins or triplets, or having a miscarriage. However, the specification only provides a written description of the specific mutations as set forth in Figure 4, and claimed in claims 56, 64, and 65. The two relevant inquiries regarding this issue are: have a representative number of species been described by complete structure; and if not, have a representative number of species been described by sufficient relevant identifying characteristics. It is submitted that the answer is in the negative for both of these questions, and as such the genus claims cannot be justified. While the specification discloses 19 gene-level mutations

and their corresponding amino acid-level mutations, there is no description of any and every mutation which occurs in the BMPR2 gene/protein, not to mention which ones correlate with a specific disease/condition and which are neutral polymorphisms. In summary, at the time of the invention the inventors were clearly not in possession of the subject matter embodied in the generic method claims.

3. With respect to the above rejection, the arguments of the response filed 12/09/03 have been fully considered, but are not found persuasive. The response argues that the specification satisfies the criteria for establishing that the instant inventors were in possession of the invention as claimed at the time of the invention. However, the Office disagrees with this conclusion as discussed in the rejection. The specification discloses 19 species of mutations in the BMPR2 nucleic acid or protein which correlate with the conditions of a pulmonary disease, multiple birth, or miscarriage. The claims in question seek protection for methods of detecting the genus of any and every possible relevant mutation with respect to said conditions. While the fact that 19 species have been disclosed by Applicants must be considered, the potential size of the genus must also be factored in. The Loyd et al. publications and patents, while not prior art, provide evidence that the genus of such mutations is likely large, as they disclose 8 mutations not disclosed in the instant application. Thus, at the very minimum, the genus being claimed encompasses 8 mutations which are in no way described in the instant specification, and thus the inventors were clearly not in possession of them. For this reason, it is believed that the instant specification does not satisfy the criteria for written

description regarding the claims in question, and that protection for the genus as claimed cannot be justified.

4. Claim 56 is allowable. Claims 64 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art has been found teaching or suggesting detection of the specified mutations in the BMPR2 gene/protein and correlating them with predisposition to/affliction of a pulmonary disease, having twins or triplets, or having a miscarriage.

5. Loyd et al. (US 6,642,002), which is not prior art, is made of record as a reference of interest. This reference discloses several BMPR2 mutations which are correlated with pulmonary hypertension, some of which are disclosed in the instant application and some of which are not.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

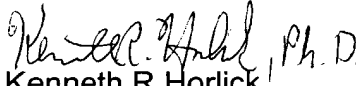
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

2/23/04